

<ANNEX III> [For referral procedures]

**SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET**

SUMMARY OF PRODUCT CHARACTERISTICS

<▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.> [For medicinal products subject to additional monitoring ONLY]

1. NAME OF THE MEDICINAL PRODUCT

<{(Invented) name strength pharmaceutical form}>

<{(Invented) name and associated names (see Annex I) strength pharmaceutical form}>

<[See Annex I - To be completed nationally]> [For referral procedures]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s) with known effect>

<For the full list of excipients, see section 6.1.>

<[To be completed nationally]> [For referral procedures, as appropriate]

3. PHARMACEUTICAL FORM

<[To be completed nationally]>

<The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The score line is not intended for breaking the tablet.>

<The tablet can be divided into equal doses.>

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

<This medicinal product is for diagnostic use only.>

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>.>

4.2 Posology and method of administration

Posology

Paediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> [or any other relevant subsets, e.g. weight, pubertal age, gender] <has> <have> not <yet> been established.>

<No data are available.> <Currently available data are described in section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

<{X} should not be used in children aged {x to y} <years> <months> [or any other relevant subsets, e.g. weight, pubertal age, gender] because of <safety> <efficacy> concern(s).>

<There is no relevant use of {X} <in the paediatric population> <in children aged {x to y} <years>, <months> [or any other relevant subsets, e.g. weight, pubertal age, gender] <for the indication of...>.>

<{X} is contraindicated in children aged {x to y} <years> <months> [or any other relevant subsets, e.g. weight, pubertal age, gender] <for the indication of...> (see section 4.3).>

Method of administration

<Precautions to be taken before handling or administering the medicinal product>

<For instructions on <reconstitution> <dilution> of the medicinal product before administration, see section <6.6> <and> <12>.>

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.>

Paediatric population

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

Paediatric population

<Interaction studies have only been performed in adults.>

4.6 Fertility, pregnancy and lactation

Pregnancy

Breastfeeding

Fertility

4.7 Effects on ability to drive and use machines

<{(Invented) name} has <no or negligible influence> <minor influence> <moderate influence>

<major influence> on the ability to drive and use machines.>

<Not relevant.>

4.8 Undesirable effects

Paediatric population

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#).*

[*For the printed material, and national translations:

For MRP and DCP procedures: The actual details of the national reporting system (as listed in [Appendix V](#)) of the concerned Member State(s) shall be displayed on the printed version and may also be displayed in the electronic national translation, published or not published. No reference to [Appendix V](#) should

be included in the printed materials. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used.

For referral procedures: Please refer to the guidance in the annotated QRD template for centralised procedures.]

4.9 Overdose

<Paediatric population>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: <{code}> <not yet assigned>

<{(Invented) name}> is a biosimilar medicinal product. Detailed information is available on the website of {name of Member State/Agency}>

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Paediatric population>

<The European Medicines Agency has waived the obligation to submit the results of studies with <{(Invented) name}> [or for generics: <the reference medicinal product containing {name of the active substance(s)}>] in all subsets of the paediatric population in {condition as per paediatric investigation plan (PIP) decision, for the granted indication} (see section 4.2 for information on paediatric use).>

<The European Medicines Agency has deferred the obligation to submit the results of studies with <{(Invented) name}> [or for generics: <the reference medicinal product containing {name of the active substance(s)}>] in one or more subsets of the paediatric population in {condition, as per paediatric investigation plan (PIP) decision, for the granted indication} (see section 4.2 for information on paediatric use).>

<This medicinal product has been authorised under “Exceptional Circumstances”. This means that <due to the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product.

{Name of Member State/Agency} will review any new information which may become available every year and this SmPC will be updated as necessary>

<The reference medicinal product containing {active substance} has been authorised under ‘exceptional circumstances’. This means that <due to the rarity of the disease><for scientific reasons><for ethical reasons> it has not been possible to obtain complete information on the reference medicinal product. {Name of Member State/Agency} will review any new information which may become available every year and this SmPC will be updated as necessary accordingly to the reference medicinal product SmPC.>

5.2 Pharmacokinetic properties

<Absorption>

<Distribution>

<Biotransformation>

<Elimination>

<Linearity/non-linearity>

<Pharmacokinetic/pharmacodynamic relationship(s)>

5.3 Preclinical safety data

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.>

<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>

<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Environmental risk assessment (ERA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<None.>

<[To be completed nationally]> *[For referral procedures, as appropriate]*

6.2 Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in section <6.6> <and> <12>.>

<[To be completed nationally]> *[For referral procedures, as appropriate]*

6.3 Shelf life

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

<[To be completed nationally]> *[For referral procedures, as appropriate]*

6.4 Special precautions for storage

<For storage conditions after <reconstitution> <dilution> <first opening> of the medicinal product, see section 6.3>

<[To be completed nationally]> *[For referral procedures, as appropriate]*

6.5 Nature and contents of container

<Not all pack sizes may be marketed.>

<[To be completed nationally]> *[For referral procedures, as appropriate]*

6.6 Special precautions for disposal <and other handling>

<Use in the paediatric population>

<No special requirements <for disposal>.>

<Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: {DD month YYYY}>

<Date of latest renewal: {DD month YYYY}>

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

<[To be completed nationally]>

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>

<Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>

<Detailed information on this medicinal product is available on the website of {name of Member State Agency (link)}>

LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

<{(Invented) name strength pharmaceutical form}>

<{(Invented) name and associated names (see Annex I) strength pharmaceutical form}>
<[See Annex I - To be completed nationally]> [For referral procedures]

{active substance(s)}

2. STATEMENT OF ACTIVE SUBSTANCE(S)

3. LIST OF EXCIPIENTS

<[To be completed nationally]> [For referral procedures, as appropriate]

4. PHARMACEUTICAL FORM AND CONTENTS

<[To be completed nationally]> [For referral procedures, as appropriate]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

9. SPECIAL STORAGE CONDITIONS

<[To be completed nationally]> [For referral procedures, as appropriate]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

<[To be completed nationally]> *[For referral procedures]*

16. INFORMATION IN BRAILLE

<Justification for not including Braille accepted.>

<[To be completed nationally]> *[For referral procedures]*

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

<Not applicable.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

< PC {number} [product code]

SN {number} [serial number]

NN {number} [national reimbursement number or other national number identifying the medicinal product]>

<Not applicable.>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

<{(Invented) name and associated names (see Annex I) strength pharmaceutical form}>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{active substance(s)}

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{Name}

3. EXPIRY DATE

4. BATCH NUMBER

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

{(Invented) name strength pharmaceutical form}

<{(Invented) name and associated names (see Annex I) strength pharmaceutical form}>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{active substance(s)}

{Route of administration}

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

4. BATCH NUMBER

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

<[To be completed nationally]> *[For referral procedures, as appropriate]*

6. OTHER

PACKAGE LEAFLET

Package leaflet: Information for the <patient> <user>

<{(Invented) name strength pharmaceutical form}>

<{(Invented) name and associated names (see Annex I) strength pharmaceutical form}>

<[See Annex I - To be completed nationally]> [For referral procedures]

{active substance(s)}

<▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.> [For medicinal products subject to additional monitoring ONLY]

<Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <,> <or> <pharmacist> <or nurse>.
- <- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.>
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.>

<Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.

Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days.>>

<[To be completed nationally]>

What is in this leaflet

1. What X is and what it is used for
2. What you need to know before you <take> <use> X
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Contents of the pack and other information

1. What X is and what it is used for

<You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days.>>

2. What you need to know before you <take> <use> X

Do not <take> <use> X

- <if you are allergic to {active substance(s)} or any of the other ingredients of this medicine (listed in section 6).>

Warnings and precautions

Talk to your doctor <or> <,> <pharmacist> <or nurse> before <taking> <using> X.

Children <and adolescents>

Other medicines and X

<Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or might <take> <use> any other medicines.>

X with <food> <and> <, > <drink> <and> <alcohol>

Pregnancy <and> <, > breast-feeding <and> fertility>

<If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your <doctor> <or> <pharmacist> for advice before taking this medicine.>

Driving and using machines

<X contains {name the excipient(s)}>

<[To be completed nationally]> *[For referral procedures, as appropriate]*

3. How to <take> <use> X

<Always <take> <use> this medicine exactly as your doctor <or pharmacist> has told you. Check with your <doctor> <or> <pharmacist> if you are not sure.>

<The recommended dose is...>

<Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <, > <or> <pharmacist> <or nurse> <has> <have> told you. Check with your <doctor> <or> <, > <pharmacist> <or nurse> if you are not sure.>

<The recommended dose is...>

<Use in children <and adolescents>>

<The score line is only there to help you break the tablet if you have difficulty swallowing it whole.>

<The tablet can be divided into equal doses.>

<The score line is not intended for breaking the tablet.>

<If you <take> <use> more X than you should>

<If you forget to <take> <use> X>

<Do not take a double dose to make up for a forgotten <tablet> <dose> <...>.>

<If you stop <taking> <using> X>

<If you have any further questions on the use of this medicine, ask your <doctor> <, > <or> <pharmacist>< or nurse>.>

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

<Additional side effects in children <and adolescents>>

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <, > <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national

reporting system listed in [Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

[*For the printed material, and national translations:

For MRP and DCP procedures: The actual details of the national reporting system (as listed in [Appendix V](#)) of the concerned Member State(s) shall be displayed on the printed version and may also be displayed in the electronic national translation, published or not published. No reference to [Appendix V](#) should be included in the printed materials. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used.

For referral procedures: Please refer to the guidance in the annotated QRD template for centralised procedures.]

5. How to store X

<[To be completed nationally]> *[For referral procedures, as appropriate]*

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}>. <The expiry date refers to the last day of that month.>

<Do not use this medicine if you notice {description of the visible signs of deterioration}>.

<Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.>

6. Contents of the pack and other information

What X contains

- The active substance(s) is (are)...
- The other <ingredient(s)> <(excipient(s))> is (are)...
<[To be completed nationally]> *[For referral procedures, as appropriate]*

What X looks like and contents of the pack

<[To be completed nationally]> *[For referral procedures, as appropriate]*

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

<**This medicinal product is authorised in the Member States of the [European Economic Area](#) <and in the United Kingdom (Northern Ireland)> under the following names:>**

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

<United Kingdom (Northern Ireland)> <{Name of the medicine}>

<[See Annex I - To be completed nationally]> [For referral procedures, as appropriate]

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>

<This medicine has been authorised under “exceptional circumstances”. This means that <because of the rarity of this disease> <for scientific reasons> <for ethical reasons> it has been impossible to get complete information on this medicine. {Name of Member State/Agency} will review any new information on this medicine every year and this leaflet will be updated as necessary.>

<X contains the same active substance and works in the same way as a ‘reference medicine’ already authorised in the EU. The reference medicine for X has been authorised under ‘exceptional circumstances’. This means that <because of the rarity of this disease><due to scientific reasons> <due to ethical reasons> it has been impossible to get complete information on the reference medicine. {Name of Member State/Agency} will review any new information on the reference medicine every year and any updates for the reference medicine will also be included as appropriate in the information for X, such as this leaflet.>

<Other sources of information>

<Detailed information on this medicine is available on the website of {name of Member State Agency (link)}>

<----->

<The following information is intended for healthcare professionals only:>